SMG 1291.11

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drugs Evaluation and Research

Office of Generic Drugs

Office of Research and Standards

Division of Therapeutic Performance I

Effective Date: October 9, 2020

1. Division of Therapeutic Performance I (DCDMAA).

A. Conducts regulatory science research to support development of generic drug products for the American public.

B. Conducts regulatory science research to establish equivalence standards for generic drugs that will ensure therapeutic equivalence.

C. Provides pre-submission scientific advice to Abbreviated New Drug Applications (ANDAs) sponsors of applications submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act on equivalence standards for generic drugs including complex products.

D. Ensures the therapeutic equivalence of approved generic drugs through post-approval research and investigation of potential safety, product use issues or bioequivalence problems.

E. Manages the pre-ANDA meeting process to provide scientific advice for generic drug development.

F. Develops product specific guidance(s) for complex products that provide timely and clear advice to generic drug developers.

2. Authority and Effective Date.

The functional statements for the Division of Therapeutic Performance I were approved by Commissioner of Food and Drugs on September 8, 2020, and effective on October 9, 2020.

Department of Health and Human Services
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Center for Drug Evaluation and Research
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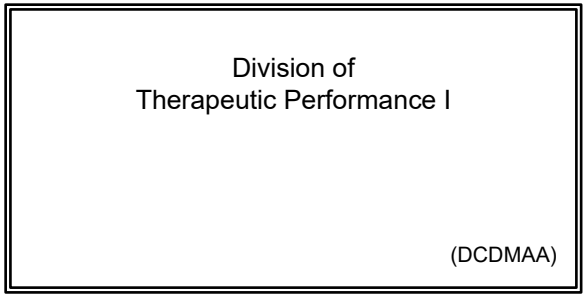
Division of Therapeutic Performance I



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Generic Drugs, Office of Research and Standards, Division of Therapeutic Performance I, organization structure depicting all the organizational structures reporting to the Director:

Division of Therapeutic Performance I (DCDMAA).